Press release

Stockholm, Sweden, 12 December 2025

Sobi Receives Positive CHMP Opinion for Aspaveli® (pegcetacoplan) for the Treatment of C3G and Primary IC-MPGN

· *Approximately 8,000 people in Europe are living with C3G or primary IC-MPGN*

· *If approved, Aspaveli (pegcetacoplan) would be the first C3G and primary IC-MPGN treatment for patients 12 and older*

Sobi® (STO: SOBI) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending the marketing authorisation of Aspaveli® (pegcetacoplan) for the treatment of adult and adolescent patients with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN).

The positive opinion from the CHMP is now referred to the European Commission for an approval decision, which is expected in the first quarter of 2026. Sobi and its partner Apellis Pharmaceuticals, Inc. have global co-development rights for systemic pegcetacoplan.

"The CHMP's positive opinion for Aspaveli represents an important milestone for people living with C3G or primary IC-MPGN in Europe, two severe and rare kidney diseases with limited treatment options and a high risk of kidney failure," said Lydia Abad-Franch, MD, Head of R&D and Medical Affairs, and Chief Medical Officer at Sobi. "If approved, Aspaveli would become the first therapy for patients 12 years and older with these serious kidney diseases, which often affect adolescents and young adults. We look forward to the European Commission's decision and to the opportunity to make a meaningful difference in the lives of patients and their families."

C3G and primary IC-MPGN are rare kidney diseases affecting approximately 8,000 patients in Europe. More than half of people living with C3G or primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or dialysis therapy.[1-3]

The CHMP recommendation is based on positive results from the Phase 3 VALIANT study, in which Aspaveli demonstrated benefits across three key markers of disease, including significant reduction in proteinuria, stabilisation of kidney function, and substantial clearance of C3 deposits. These positive results were recently published in The New England Journal of Medicine.[6]

About C3 Glomerulopathy (C3G) and Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)
C3G and primary IC-MPGN are rare and debilitating kidney diseases that can lead to kidney failure. Excessive C3 deposits are a key marker of disease activity, which can lead to kidney inflammation, damage, and failure. Approximately 50% of people living with C3G or primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or dialysis therapy.[1-3] Additionally, approximately 90% of patients who previously received a kidney transplant will experience disease recurrence.[4] The diseases are estimated to affect 5,000 people in the United States and up to 8,000 in Europe.[5]

About the VALIANT Study
The VALIANT Phase 3 study (NCT05067127) was a randomised, placebo-controlled, double-blinded, multi-center study that evaluated pegcetacoplan efficacy and safety in 124 patients who were 12 years of age and older with C3G or primary IC-MPGN. It is the largest single trial conducted in these populations and the only study to include paediatric and adult patients, with native and post-transplant kidneys. Study participants were randomised to receive pegcetacoplan or placebo twice weekly for 26 weeks. Following this 26-week randomised controlled period, patients were able to proceed to a 26-week open-label phase in which all patients received pegcetacoplan. The primary endpoint of the study was the log transformed ratio of urine protein-to-creatinine ratio (UPCR) at Week 26 compared to baseline.

About Aspaveli®/Empaveli® (pegcetacoplan)
Aspaveli/Empaveli (pegcetacoplan) is a targeted C3 and C3b therapy designed to regulate excessive activation of the complement cascade, part of the body's immune system, which can lead to the onset and progression of many serious diseases. It is the first treatment approved in the United States for C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in patients 12 years of age and older, to reduce proteinuria. Aspaveli/Empaveli is also approved for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH) in the United States, European Union, and other countries globally, and for adults and adolescents with C3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in Saudi Arabia, South Korea and Switzerland.

About the Sobi® and Apellis® Collaboration
Apellis and Sobi have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-U.S. commercialisation rights for systemic pegcetacoplan. Apellis has exclusive U.S. commercialisation rights for systemic pegcetacoplan and worldwide commercial rights for ophthalmological pegcetacoplan, including for geographic atrophy.

Sobi®
Sobi is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2024, revenue amounted to SEK 26 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here.

References
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